equivital

EQ02+ SERIES
EX LIFEMONITOR

User Guide

equivital.com

EC REP

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CE

MDD 2797
ATEX 2575

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List of Abbreviations

AC	Alternating current
AM	Amplitude modulation

BPM	Beats per minute
BR	Breathing Rate
CMRR	Common mode rejection ratio
DC	Direct current
ECG	Electrocardiogram
EDR	ECG derived respiration
EMC	Electromagnetic compatibility
FDA	Food and Drug Administration
HCP	Health Care Practitioner
HR	Heart Rate
IBI	Inter-beat interval (See R-R interval)
IR	Infrared
POST	Power-on self-test
PPE	Personal Protective Equipment
PWI	Physiological Welfare Index
QRS-T	Notation to identify key features of an ECG beat waveform
RH	Relative humidity
RPM	Respirations per minute
R-R	Interval time between the R wave peaks of the recorded QRS complex
SD	Secure Digital
SEM	Sensor Electronics Module

1 Introduction

This Guide provides key information pertaining to the use of the Equivital™ EX LifeMonitor and a general guide to the fitting and operation of the monitoring system. It provides an overview of all products available to use with the Equivital™ EX LifeMonitor so that you can maximize the use of the system.

This guide also contains the EQ02+ Healthcare Practitioner's (HCP) Guide - A reference section, specifically for use by healthcare practitioners, providing key information relating to the methodology of physiological data measurement.

1.1 User Guide - latest version

Please note that this Equivital™ EX LifeMonitor User Guide is updated on a regular basis.

Please register on the Equivital Helpdesk for access to the latest version of this User Guide and other customer support:

https://support.equivital.com

1.2 Getting Help

If at any point during the installation, configuration and use of the Equivital™ EX LifeMonitor you encounter problems that you cannot resolve and that are not addressed in this Installation and User Guide, please contact your local Equivital Sales Representative or contact us directly via one of the contact methods below:

Tel: +44 (0) 1954 233430

Fax: +44 (0) 1954 233431

Email: support@equivital.com

Monday to Friday 9am to 5pm (United Kingdom). If you require support outside of these hours, we can arrange a support call by appointment.

1.3 Warning, Cautions and Information

The following symbols will appear throughout this Installation and User Guide to advise of any particular dangers or to provide information that may prove useful.

Warnings are provided where there is an immediate danger to Subjects (those wearing the Equivital LifeMonitor) and/or Users (those configuring, and using the data obtained from, the Equivital LifeMonitor).

Cautions are provided where there is danger of damaging equipment or associated devices.

Information Messages are provided to assist the User in the installation and use of the products.

1.4 Intended Use Summary

The Equivital™ EX LifeMonitor is an ambulatory multi-parameter vital signs telemetry device intended for monitoring of adults (16 years and up) in hospital care facilities, the home, workplace and alternate care settings.

The device consists of a body worn sensor electronics module (SEM) connected to a fabric chest belt.

The device collects and transmits ECG data and heart rate, respiration data and rate, skin temperature, body orientation, motion and activity. Additionally, the device provides alerts and indications if physiology exceeds pre-defined boundaries.

The monitor is indicated for use as a human physiological monitor, to provide physiological and biomechanical information as part of an occupational welfare monitoring system, and for general research and performance measurement purposes.

1.5 Contraindications

The device is not intended to replace the need for appropriate medical supervision and safe practice to be provided to personnel by an operating organization.

The device is not intended for use as an apnoea monitor within a clinical context.

The device is not intended for surgical use.

The device is not intended for use on Subjects who have implanted defibrillators or pacemakers.

The device should be removed before attempting defibrillation.

The device is not intended as a diagnostic ECG monitor.

1.6 Warnings

Please observe the following warnings when using the Equivital™ EQ02+ EX LifeMonitor.

The Equivital™ EQ02+ EX LifeMonitor may be used to monitor individuals in the workplace. When used in this manner the device must be integrated into the operating organisation's safety and risk management procedures. Subjects and Users should receive appropriate training from their organisation before using this device.

Use of the device does not justify the Subject, Users or organisation to take additional safety risks or to reduce level of care.

The deploying organisation is responsible to ensure that all warnings in this document are understood and followed.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the EU competent authority of the EU Member State in which the user and/or patient is established.

This device does not automatically call emergency service assistance.

- Keep the device, belt, and charging unit away from children and pets
- The Equivital™ EQ02+ EX LifeMonitor should not be used for surgical procedures, to perform synchronised cardioversion, intracardiac monitoring, or when performing external pacing.
- The Equivital™ EQ02+ EX LifeMonitor should not be worn by Subjects who have existing signs of skin irritation and damage at the sites the device is to be located. Subjects who experience irritation or a rash should be advised to discontinue use immediately. Do not allow Subjects to wear the EX LifeMonitor for longer than 24 hours at one time.
- The Equivital™ EQ02+ EX SEM must be connected to the Equivital™ EQ02+ EX Sensor Belt by placing within its cradle pocket, and worn on-body, at all times whilst in a designated hazardous area in order to comply with the documented hazardous area certification.
- The Equivital™ EQ02+ EX LifeMonitor must not be used in areas more hazardous than those covered by the hazardous area certification documented herein and clearly displayed on the product (not packaging) labelling. It is the responsibility of the deploying organization to ensure that device labels are checked prior to deployment.
- The Equivital™ EQ02+ EX SEM is only to be charged in an area known to be non-hazardous.
- The Equivital™ EQ02+ EX SEM must not be re-charged or connected to the programming lead while being worn.
- Only Equivital™ approved accessories are to be used with the Equivital™ EQ02+ EX LifeMonitor. The safe use of the device is only guaranteed with these accessories.
- The Equivital™ EQ02+ EX LifeMonitor will NOT work with wired ancillary sensors or external battery pack.
- Equivital™ does not approve wireless ancillary sensors for use with the Equivital™ EQ02+ EX LifeMonitor in a hazardous environment.
- The use of the Equivital™ EQ02+ EX LifeMonitor does not impact/replace any existing safety protocols, practices or PPE.

All Subjects and Users must be fully trained prior to using the Equivital™ EQ02+ EX LifeMonitor.

No modifications should be made to the Equivital™ EQ02+ EX SEM or Sensor Belt.

The Equivital™ EQ02+ EX must not be disposed of as normal domestic trash. It should be handed in at a collection point for recycling electrical and electronic appliances. Do not dispose of the device using incineration.

1.7 General Precautions

Please observe the following precautions when using the Equivital™ EQ02+ EX LifeMonitor.

Lotions, oils, perfumes, deodorant or powder should not be used on the area of the body where the Sensor Belt is being fitted.

Each time an Equivital™ EQ02+ EX LifeMonitor is issued for use, it is important to inspect the EQ02+ EX SEM and EQ02+ EX Sensor Belt for signs of damage (tears/cracks etc). If any damage is identified, do not use the equipment until the damaged part has been replaced.

To get maximum performance from the system you should replace the Sensor Belt after 6 months of regular use, or if a fail is indicated by a Belt Tester unit . The Sensor Belt should be washed, using the guidelines provided, after each use.

Refer to the environmental specifications in this document to see the environmental conditions (e.g. ambient temperature) within which the Equivital™ EQ02+ EX LifeMonitor should be operated.

When initially worn the Equivital™ EQ02 EX LifeMonitor should be given time for the data signals to stabilise.

When using your EQ02+ EX SEM for the first time please remove the protective film cover from the display LEDs on the front of the SEM

The EQ02+ EX SEM shall not be charged at temperatures below 10°C, as this will significantly reduce the charge retained by the EX SEM and hence the available operating time. It is recommended to charge the EX SEM above 20°C.

The EQ02+ EX SEM should be re-charged a minimum of once every 6 months.

1.8 EQ02+ EX LifeMonitor Hazardous Area Certifications

The Equivital™ EQ02+ EX LifeMonitor can be used in environments where there is an explosive risk, in Europe and North America, as well as other countries that recognize any of the below market clearances.

Intertek 4008149

Conforms To UL Std 913
Certified To CSA Std C22.2
No. 60079-0 and No. 60079-11
Class I Div.1, Group C & D, T4 Exia
-20°C ≤ Ta ≤ + 50°C

ITS13ATEX27919X
I M1 Ex ia I Ma
II 1G
Ex ia IIB T4 Ga

MDD 2797
ATEX 2575

The labelling appears on the EQ02+ EX SEM as Figure 1. It is important to note that the market clearances and labelling applies to both the EQ02+ EX SEM and EQ02+ EX Sensor Belt.

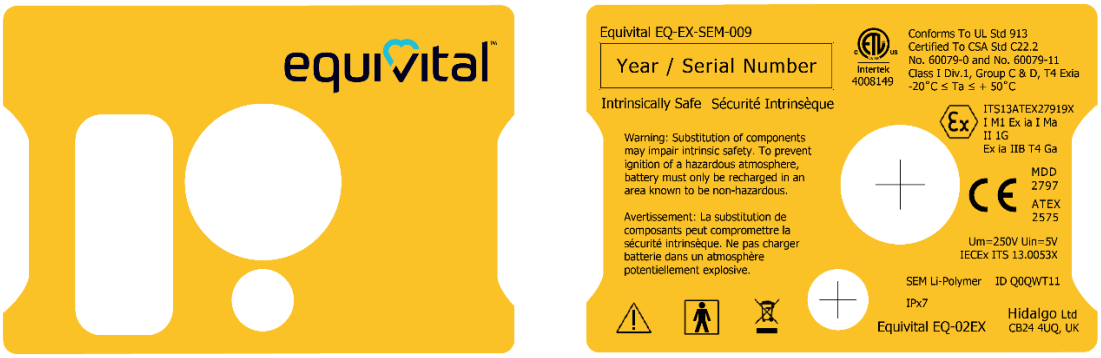

Figure 1 Labelling on EQ02+ EX SEM

The User must ensure that the Equivital™ EQ02+ EX LifeMonitor certification level is sufficient to cover use in the desired hazardous area.

2 Overview of Equivital™ EQ02+ EX LifeMonitor and Related Products

This section describes all the Equivital™ EQ02+ EX LifeMonitor products and related accessories.

The Equivital™ EX LifeMonitor is a flexible and powerful physiological monitoring device that can be used in many scenarios as per its intended use. The components of the system are as follows: -

2.1 EQ02+ EX LifeMonitor

- **EQ02+ EX Sensor Electronic Module (SEM)** – The EX SEM measures physiological and biomechanical data from the Subject. It collects ECG and Breathing Waveforms, Skin Temperature, Tri-axis accelerometer and can derive other measures within the device. It can store up to 8 GB worth of data and transmit it to the Equivital™ Manager via in-built Bluetooth capability.

- **EQ02+ EX Sensor Belt** – The EX Sensor Belt holds the EX SEM onto the Subject's body. It contains fabric electrodes that make contact with the Subject's skin to provide physiological and biomechanical data incorporates a band to measure breathing and provides an electrical connection to the EX SEM. The EX Sensor Belt is made of electrostatic discharge material.

2.2 LifeMonitor Accessories

The following accessories are to be used for charging the EX SEMs or for receiving data transmitted by the EX SEM using Bluetooth directly onto a laptop or PC, **outside of a hazardous area.**

LifeMonitor Accessories are NOT approved for use in a hazardous area

- **SEM Lead –** Allows a single EQ02+ EX SEM to be charged and configured via a standard USB connection from a Windows laptop or PC. It also enables the EX SEM to be configured or for data from it to be downloaded.

- **M Dock** – Allows up to six EQ02+ EX SEMs to be docked. The M Docks can be linked together to form a chain of up to 4 M Docks/24 EX SEMs. The M Dock has its own power supply to charge the EX SEMs that are docked but it also has a USB connection to allow the EX SEMs to be configured and for data from the EX SEMs to be downloaded.

- **Equivital™ Bluetooth Dongle** - The Class I Bluetooth dongle allows up to 6 EX SEMs in partial disclosure, and 3 in full disclosure, to communicate with a laptop or PC running Equivital™ Manager.

  The dongle is a plug-and-play USB device that does not require any additional drivers to be installed on your laptop or PC, simply plug into any available USB socket.

  For technical information please refer to Equivital™ Bluetooth Dongle Specification in the Appendix of this document.

The Equivital™ Bluetooth Dongle is NOT approved for use in a hazardous area

The Equivital™ Bluetooth Dongle is not approved for use closer than within 25cm of the body. If your application requires closer contact to the body, additional approvals will be required.

Information on connecting the dongle to the Equivital™ Distributed Network (EDN), can be found in the Equivital™ Manager User Guide.

The LED indications on the Equivital™ Bluetooth Dongle are as follows:

- Solid Green LED – Power on
- Slow Flashing Blue LED – Device Ready
- Solid Blue LED – Searching for devices
- Fast Flashing Blue LED – Sending or Receiving Data

The Equivital™ Bluetooth Dongle will not give you access to third party Bluetooth devices. Inserting your dongle will not enable Bluetooth services on your PC or laptop.

2.3 LifeMonitor Ancillary Wireless Sensors

Information on ancillary wireless sensors for use outside of a hazardous area can be found in the EQ02+ Series LifeMonitor Guide, HIDA3330-IFU-39.

LifeMonitor Ancillary Wireless Sensors are NOT approved for use in a hazardous area

3 Equivital™ EQ02+ EX LifeMonitor

The Equivital™ EQ02+ EX LifeMonitor comprises the EX SEM and the EX Sensor Belt.

3.1 EQ02+ EX Sensor Electronics Module (SEM)

Figure 2 EX SEM showing the buttons and indicators

When using your EQ02+ SEM for the first time please remove the protective film cover from the display LEDs on the front of the SEM

Switching the EX SEM ON & OFF

Switching the EX SEM On

- Press and hold the EX SEM on/off button until the Power LED illuminates GREEN and the Event LED illuminates RED
- Release the button.
- The Power LED will continue to flash GREEN for approximately 30 seconds
- To check the EX SEM is on at any time, short press the on/off button. At minimum the Power LED will flash GREEN 5 times (see important LED indications)

Switching the EX SEM Off

- Press and hold the EX SEM on/off button until the AMBER LED FLASHES and then turns to RED LED
- Release the button and the EX SEM will turn off.

For certain uses you may wish to completely disable the off functionality of the power button. This ensures the EX SEM cannot be manually switched off using the power button. For more information on power options please see Equivital™ Manager User Guide

Additional On/Off Button Features

As well as switching the EX SEM on or off, the on/off button can also be used to signal an event or alert. The precise function and use of these features will vary depending upon the nature of the application.

Event Marker/Alert

- Press and hold the EX SEM on/off button for 0.5 second until the AMBER LED flashes. An event marker will be placed into the SEM file.

Charged Indicator

- When the EX SEM is connected to a charging unit, either a SEM Lead or M Dock, and has reached a good charge level the on/off will illuminate SOLID GREEN .

EX SEM LED Definition

Icon	LED	Indicates a function
	POWER GREEN	• When the EX SEM is turned on by pressing the front button for at least 3 seconds the Power LED lights up GREEN, and flashes for approximately 30 seconds. • If the EX SEM is on when the front button is pressed, the Power LED is immediately illuminated and flashes GREEN a minimum of five times. • Lights up GREEN when the EX SEM is fully charged or the EX SEM has a good charge level.

Icon	LED	Indicates a function
	**CHARGE** GREEN/AMBER	• Illuminates briefly during start up. • Flashes GREEN to indicate charging. • Flashes AMBER LED to indicate a low battery condition.
	**EVENT** RED/AMBER	• Illuminates briefly during start up. If a POST failure occurs the LED flashes RED until the EX SEM is turned off • If the front button is held for more than 0.5 seconds, the AMBER LED starts to flash, indicating that the EX SEM has been primed to create an event marker message. • If the front button is pressed for more than 3 seconds the RED LED turns on, and the EX SEM is set to turn off. The EX SEM turns off when the front button is released.
	**DATA** BLUE	• The BLUE Data LED is flashed briefly when a core pill or dermal patch transmission is received. • The BLUE Data LED is flashed 3 times when the EX SEM is paired over Bluetooth or if it receives a Bluetooth ancillary reading.

Table 1 EX SEM LED Definitions

Other Important LED Indications

With the EX SEM switched on, press the on/off button for less than 0.5 seconds. The EX SEM will enter an indication period indicated by a flashing green power light. The status of the EX SEM will be shown as follows:

When SD card logging is active. The  LED flashes slow, AMBER.

When SD card logging is active but data cannot be written to the SD card. The  LED flashes slow RED.

When SD card logging is inactive, the Event LED (!) is OFF.

When SD card logging is active, but has stopped unexpectedly, the  LED is solid RED.

When Bluetooth is connected, the  LED flashes slowly.

When Bluetooth is enabled, but not connected, the  LED flashes quickly.

When Bluetooth is disabled, the Data LED is off ().

When Core Pill detection is enabled and a core pill is detected, the  LED charging light flashes slowly GREEN.

EX SEM Recharging

When the battery level is low the LED will flash continuously AMBER.

From the time at which the LED starts to flash AMBER, the EX SEM will function normally for a minimum period of 20 minutes (the actual time will depend on EX SEM settings and any ancillary sensors connected).

A single SEM USB lead and Multi Dock (MDock) are available for charging EQ02+ EX SEMs.

If the SEM is charging, the LED on the SEM will flash GREEN.

When the SEM has reached a good charge level the on/off will illuminate SOLID GREEN

When the EX SEM is charged, which takes around 2.5 hours from flat, simply remove the EX SEM from the charger unit. The EX SEM is then ready for use. If you wish to check precisely how much charge is in the EX SEM open Equivital™ Manager and check on the SEM Status screen.

Do NOT recharge the Equivital™ EQ02+ EX SEM in a

The Equivital™ EQ02+ EX SEM must not be re-charged or programming lead while being worn

The EX SEM shall not be charged at temperatures below
significantly reduce the charge retained by the SEM
operating time. It is recommended to charge t

The EX SEM should be re-charged a minimum of once every 6 months

Keeping the EX SEM on charge after On/Off has illuminated SOLID GREEN will further increase the charge level. Charge level can be checked in Equivital™ Manager.

Docking an EX SEM to the M Dock

- Push the EX SEM into M Dock with the top side facing forward.
- Once the EX SEM is pushed firmly into the M Dock the EX SEM will begin charging

Attaching an EX SEM to the Single Lead

- Push the Single Lead into the EX-SEM, ensuring the Connector Lead is the correct way up. The Connecter is marked 'TOP' and this should be facing upward.
- Connect the other end into a USB slot on your PC and the EX SEM will begin charging.

EQ02+ EX SEM charging accessories, M Dock and Single Lead are NOT approved for use in a hazardous area

Never connect the Equivital™ supplied mains connected battery charger or programming lead to the Equivital™ EQ02+ EX SEM or EX Sensor Belt when the system is on-body.

Ensure that you have checked with your system operator or health care practitioner on how to reconnect your EQ02+ EX SEM to the appropriate receiving station or monitoring point.

When you connect the first EX SEM to your PC, Windows will automatically load drivers, which will take a few seconds. For subsequent connection of this, or other, EX SEMs drivers will automatically loaded in the background.

3.2 EQ02+ EX Sensor Belt

Only the Equivital™ EQ02+ EX Sensor Belt should be used with the EQ02+ EX SEM, in order to comply with the hazardous area certification listed in this document, and clearly labelled on the EQ02+ EX SEM.

The EQ02+ EX Sensor Belt is clearly labelled for use in hazardous areas in conjunction with the EQ02+ EX SEM. The User should check the EQ02+ EX Sensor Belt labelling to ensure the correct EX Sensor Belt is being used prior to use in a hazardous area.

The EQ02+ EX Sensor Belt is shown in Figure 3. The Sensor Belt contains fabric electrodes that measure vital signs when in good contact with the Subject's skin. The Sensor Belt also holds the EX SEM securely on-body.

The EX Sensor Belt is made from a breathable, lightweight fabric to ensure that it is comfortable for long-term use. The two-shoulder strap unisex design provides a secure and comfortable fit for Subjects.

The Sensor Belt should be worn as shown in Figure 3, with the two straps over the shoulders and the torso clasp placed centrally on the front of the body.

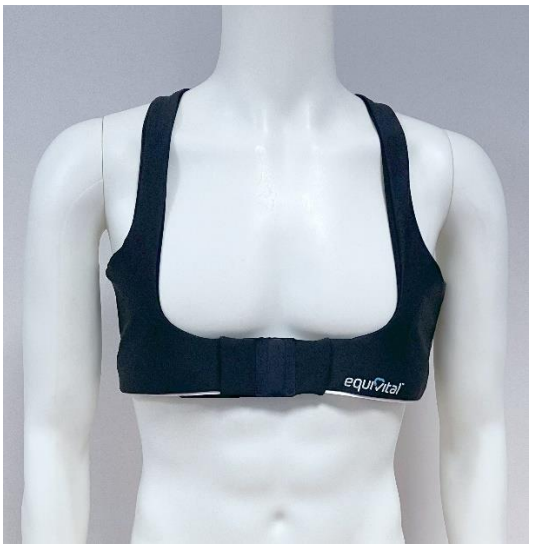

Figure 3 Wearing the EX Sensor Belt

Sensor Belt Fitting Instructions

A well fit belt is essential for collecting good quality data from the LifeMonitor; it is recommended that a belt should be fitted to the body such that it does not move during use. The sensor belt should be positioned in line with your breastbone. When positioned correctly the belt connection clasp should be central to the chest and the shoulder straps should provide gentle support without being tightly strained.

It is important that the wearer feels comfortable donning the sensor belt.

Measuring for the Correct Sensor Belt Size

Measurement should be taken at the xiphisternum in line with the bottom of the pectoral muscles.
Positioning of the belt may be dependent on whether the belt is worn under or over a bra or sports bra (if applicable). Both are suitable for effective use.

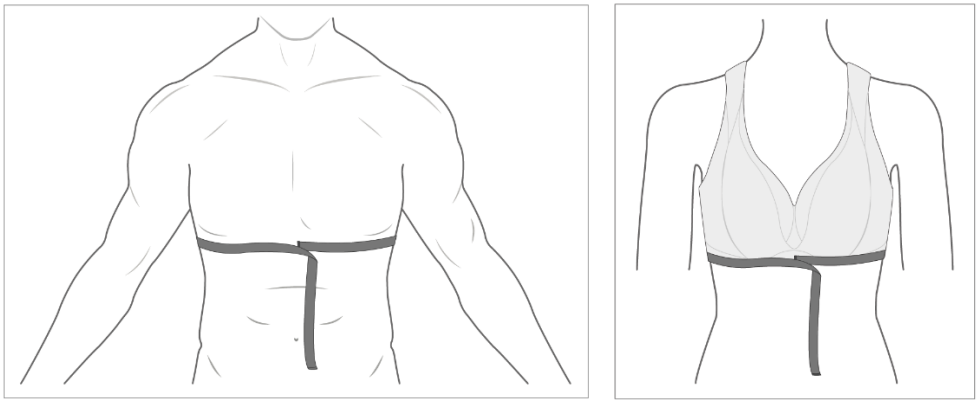

Figure 4 Measuring users for the correct sensor belt size

Note, as can be seen in Figure 4, that the measurement point is NOT the same as chest size.

Selecting the Correct Sensor Belt Size

The following sizing chart provides a guideline on how to select the correct belt size to use.

If in between sizes, try on both sizes as fit can be impacted by body shape. Wear the size with the least movement and greatest comfort when worn.

Belt Size	Chest Circumference Measurement (cm)	Chest Circumference Measurement (inches)
Small	74 - 85 cm	29 - 33.5 inches
Medium	85 - 96 cm	33.5 - 38 inches
Large	96 - 107.5 cm	38 - 42 inches
Extra Large	107.5 - 120 cm	42 - 47 inches

Table 2 Sensor Belt Sizes

How to Wear the Sensor Belt

It is essential that the three electrodes touch bare skin at all times (Fig 5).

If worn with a sports bra, this can be either over (Fig 6) or under (Fig 7). Users may have a personal preference on how to wear the belt based on comfort.

Please consult Equivital for advice if the belt seems to fit in an unusual way, for example tight in some areas and loose in others, or if the belt seems to fit too low on the subject.

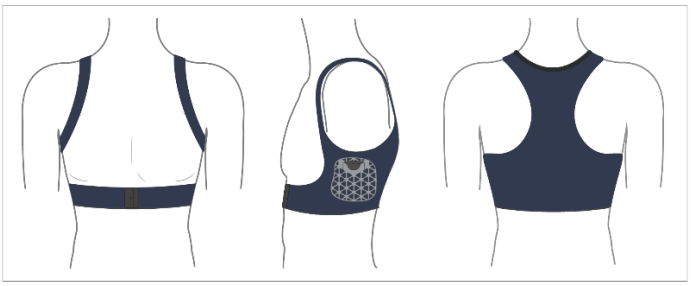

Figure 5 user wearing the sensor belt

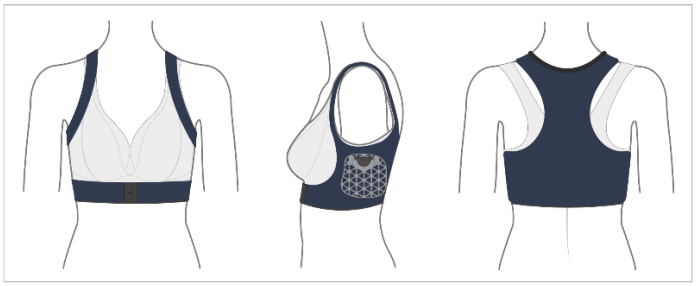

Figure 6 user wearing sensor belt over bra

Figure 7 user wearing sensor belt under bra

The best way to verify belt fit is by using the waveform view from eqView Mobile or eqView Pro and watching for a stable ECG trace while still, and during movement

Wearing the Sensor Belt

1. Moisten the three silver patches on the inside of the belt (two at the front left and right and one on the right side of the back) using clean water.

   This helps the sensor make contact with the skin to record its signals. Do not use de-ionised water or any other gel or liquid.

2. Hold the Sensor Belt by its ends with the silver-coloured patches facing inward towards the body. Place the belt around the body with fastener facing the front and both shoulder straps comfortably placed on each shoulder. There should be an approximate 5 cm separation, between the fastener as shown in Figure 8.

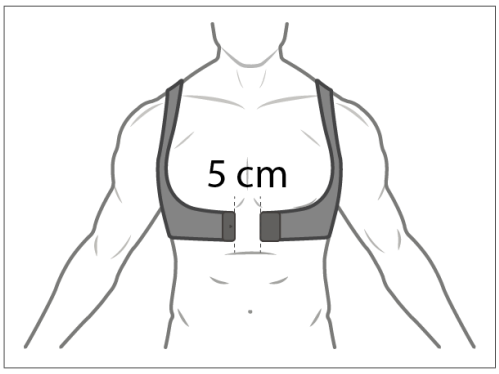

Figure 8 Fitting the EX Sensor Belt

3. Connect the hook and eye connections at each end of the main belt, selecting the setting which is most comfortable for you.

   The belt should be firmly contacting the body all around but not uncomfortable. You should be able to push your finger down between the belt and the body.

4. Gently rotate the belt so the plastic centre section is now at the front of the body near the centre of the chest.

How to identify a Correctly or Incorrectly fitted Sensor Belt

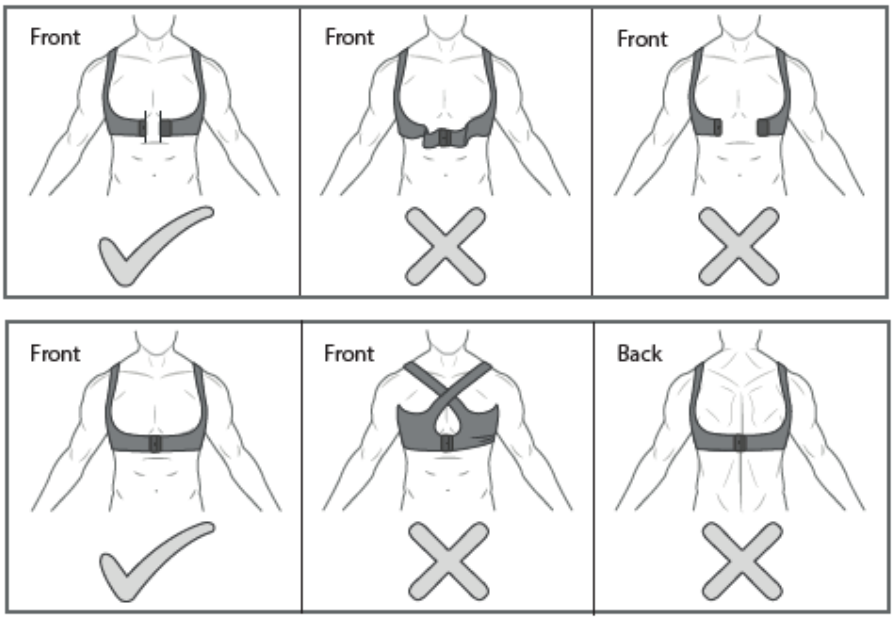

Figure 9 Sensor Belt – correct and incorrect fit

Figure 9 shows examples of a correctly and incorrectly fitted Sensor Belt.

It is essential for data quality that all three ECG electrodes of the Sensor Belt are touching bare skin at all times

The Sensor Belt should be worn under all garments and equipment

The Sensor Belt can be worn over or under a bra or sports bra. This is up to the Subjects personal comfort preference.

Do NOT overstretch the Sensor Belt as this can damage it.

Do NOT fit the belt by joining the connection and then pulling over the head and arms.

Lotions, oils, perfumes, deodorant or powder should not be used on the area of the body where the Sensor Belt is being fitted.

Before each use check the Sensor Belt for signs of damage (tears/cracks etc). If any damage is identified, do not use the equipment until the damaged part has been replaced.

Attaching the EQ02+ EX SEM

1. Switch the EQ02+ EX SEM on.
2. Insert the EQ02+ EX SEM into the cradle pocket inside the Sensor Belt making sure the SEM LED face down and are clearly visible through the cut-out in the Sensor Belt when fully connected.
3. A positive ‘click’ sound indicates a good connection.
4. Make sure the EX SEM Is switched on before wearing the LifeMonitor system. Check by pushing the power button through the belt fabric; the EQ02+ EX SEM LEDs should flash.

The Equivital™ EQ02+ EX SEM must be fully inserted within the cradle pocket of the Equivital™ EQ02+ EX Sensor Belt at all times whilst in a designated hazardous area in order to comply with the documented hazardous area certification. There should be an audible click and the SEM LEDs shall be clearly visible in the opening of the Sensor Belt cradle

5. To remove the SEM, hold the top sides of the cradle, compress slightly with one hand and pull the SEM out with the other hand.

3.3 Managing & Exporting EQ02+ SEM Data

EQ02+ SEM data can be managed and exported via Equivital™ Manager. This PC application enables the data files to be downloaded and exported in different formats. This is achieved by connecting the off-body SEM via the M Dock or SEM lead to the PC running the application. The minimum system requirements are Windows 7, 8, 8,1 or 10, 2 GB of RAM and 2 GHz processor.

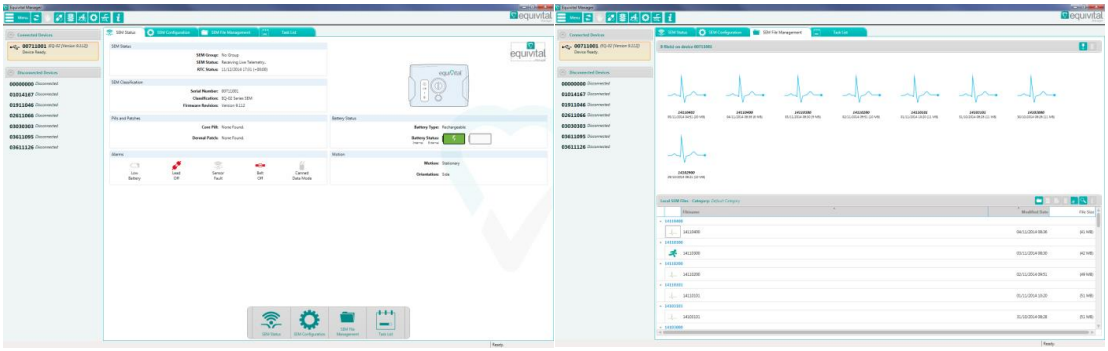

Figure 10 Equivital™ Manager screenshots showing SEM status and saved files

3.4 Washing & Cleaning

Equivital™ EQ02+ EX SEM

Wipe the EQ02+ EX SEM clean with a damp cloth or sterile wipe and leave to dry normally.

Do not place the EQ02+ EX SEM on a heat source such as a radiator

The EQ02+ EX SEM should not be immersed in, or sprayed with liquid, as this could damage the exposed connector

Equivital™ EQ02+ EX Sensor Belt

To wash the EQ02+ EX Sensor Belt

1. Fold the belt carefully and insert into a delicates wash bag.
2. Hand or Machine Wash at a low temperature (30°C) using a mild non-biological detergent with no bleaching agents.
3. Re-shape while wet and allow to drip dry.

The Sensor Belt should be washed, using the guidelines provided, before each use.

The Sensor Belt should be washed with items of similar colour

Do NOT leave the Sensor Belt to soak.

Do NOT use fabric softeners, optical brighteners or any bleaching agents

Do NOT spin or tumble dry

To maximise performance from the system you should replace the Sensor Belt after 6 months of regular use, or if a fail is indicated by a Belt Tester unit .

3.5 Troubleshooting Guide

Device doesn't power on

- Follow the instructions for power on in Section 3.1. If the LEDs do not illuminate as described then check the battery charge status by connecting the SEM to a charging unit, either a SEM Lead or M Dock. The battery LED should flash green to indicate that the unit is charging. When the unit has reached a good charge level the on/off should illuminate solid green.

Device on or off

- Short press the on/off button to check the SEM is on at any time. At minimum, the Power LED will flash green 5 times if the unit is on.

Flashing LEDs

- See Section 3.1 for LED behaviour description.

No data files on the device to download

- Device is not connected to the PC running EQM
    - Ensure the device is connected to either a SEM Lead or M Dock and that the charger is connected to the PC running EQM
- Device was not powered on or had low battery at power on

- Follow the instructions for power on in Section 3.1. If the LEDs do not illuminate as described then check the battery charge status by connecting the SEM to a charging unit, either a SEM Lead or M Dock. The battery LED should flash green to indicate that the unit is charging. When the unit has reached a good charge level the on/off should illuminate solid green.

- Wrong device being accessed on EQM
  - Compare the serial number displayed on EQM with the serial number on the device label
- SD Card Issue:
  - See Section 3.1 for information on other important LED indications that include how to check SD Card status.

Incorrect date in downloaded filename and timestamps

- Connect the EQ02+ SEM to EQM prior to use to ensure that the SEM clock is reset.

Poor download data quality

- Incorrect belt fit
  - See the belt fitting and wearing instructions in Section 3.2
- Belt no longer functioning correctly
  - To get maximum performance from the system you should replace the Sensor Belt after 6 months of regular use, or if a failure is indicated by a Belt Tester unit. The Sensor Belt should be washed, using the guidelines provided, after each use as described in Section 3.4

For further assistance please contact us using the contact details in Section 1.2

4 Healthcare Practitioner's (HCP) Guide

4.1 ECG and Heart Rate Derivation

The Equivital™ EQ02+ EX LifeMonitor provides two leads of ECG sharing a common reference electrode (Left Hand Front location).

The electrode locations within the EQ02 EX Sensor Belt are shown in Figure 11.

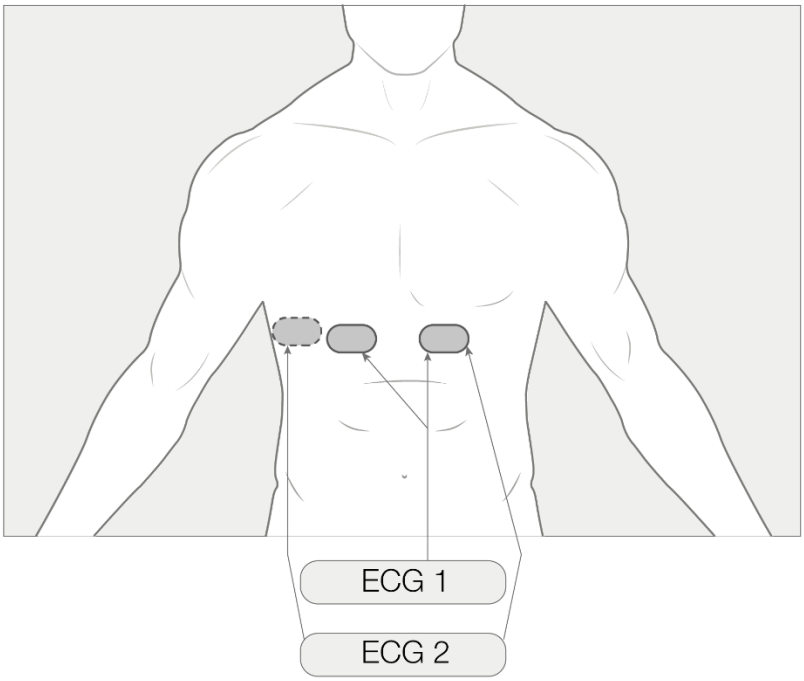

Figure 11 ECG Electrode Locations

The signal bandwidth is switchable between an ambulatory monitoring mode and a clinical/diagnostic mode.

The ambulatory filtering has been chosen to optimise R wave detection reliability under high activity (e.g., running) and removes significant amounts of the low frequency elements of the ECG waveform that are not needed.

ECG Waveforms

Figure 12 provides an example of the same ECG views in both filtering modes for comparison.

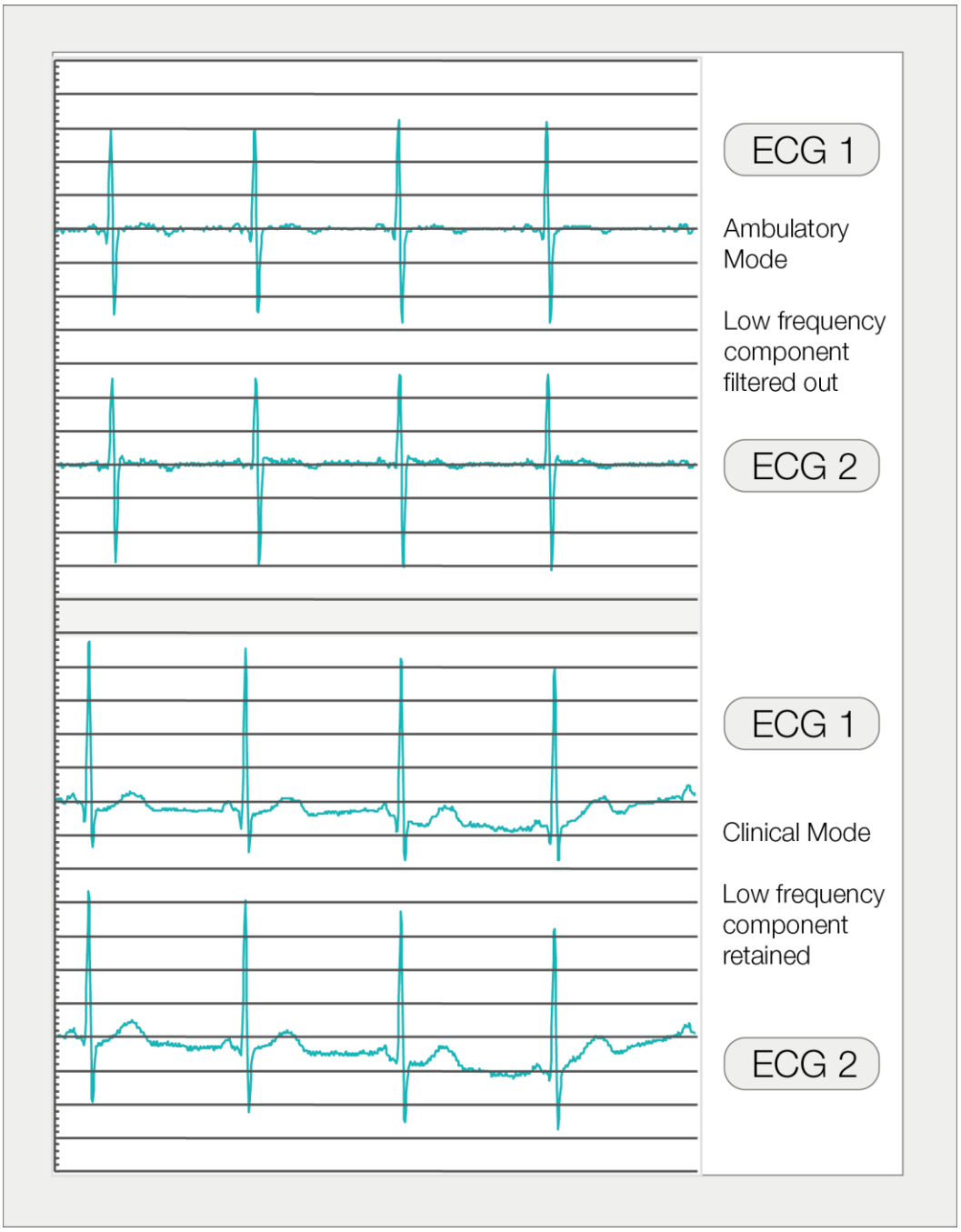

Figure 12 ECG Waveform Examples

The ECG views shown in Figure 12 show that in diagnostic mode the ECG view resembles a traditional view. However, as the views are non-standard, they are not intended to be used for diagnostic ECG screening.

The radio system used by the EQ02+ EX SEM has a variable delay in the transmission of the ECG. Hence the device waveforms displayed cannot be regarded as being exactly real-time, synchronised to the Subjects ECG.

Heart Rate Calculation

Heart Rate is calculated as a 30-second rolling average reported every 15 seconds. The Equivital™ Manager application can be used to modify the reporting time.

The sensor ECG operation has been performance tested to the American National Standard – ANSI/AAMI EC13:2002. The performance results for this testing are disclosed in the technical section at the rear of this document.

Signal Confidence and Quality Measures

A measure of signal quality is provided to assist the HCP in determining if the traces being used to compute the Heart Rates are suffering from noise/artefacts and hence that the Heart Rate accuracy may be degraded. This is particularly useful if the data is being viewed remotely from the patient/Subject.

An overall HR confidence figure is provided in the range 0-100 (100=best). This confidence measure is based on the two measures of signal quality, the amount of noise on the ECG signals and measure of large-scale variation in the inter beat interval (a clean normal sinus rhythm ECG trace will produce a high value of confidence).

The Equivital™ EQ02+ EX LifeMonitor should not be used for surgical procedures, to perform synchronised cardioversion or intracardiac monitoring, or when performing external pacing.

Note: Irregular rhythms will also act to reduce the HR confidence figure.

4.2 Breathing Frequency

The primary means of deriving breathing frequency is via an expansion sensor contained within the EX Sensor Belt, namely Expansion Derived Breathing.

As the thoracic cavity of the Subject contracts and expands with respiration effort the sensor's resistance decreases and increases, respectively. Using appropriate circuitry, this can be converted into a respiration effort rate waveform.

The overall sensitivity of the breathing detection is switched between a normal mode and a higher sensitivity mode. The latter mode is used on static, non–upright Subjects to increase breathing sensitivity to shallow breathing patterns as may be found on resting or sleeping individuals.

As with any indirect measure of breathing frequency, in this case from the measurement of chest expansion, excessive upper body motion and activity can cause artefact that will reduce the accuracy of the rate measured.

Note, the presence of breathing effort does not guarantee adequate ventilation is taking place as this is a single belt derived waveform and therefore open to inaccuracy when used to derive information on ventilation.

Breathing Rate Calculation

The Breathing rate frequency is calculated as a 60 second rolling average reported every 15 seconds.

Breathing Rate Signal Quality and Confidence Measure

An overall BR confidence (BR Conf) is also provided in the range 0-100 (100=best). This is provided to assist the HCP in determining if the traces being used to compute the Breathing Rates are suffering from noise/artefact and hence that the Breathing Rate accuracy may be degraded. This is particularly useful if the data is being viewed remotely from the patient/Subject.

4.3 Skin Temperature

Skin temperature is measured by an IR thermometer contained in the sensor module. Skin temperature is measured to a resolution of 0.1°C every 15 seconds. An initial settling time, of approximately 15-minutes, is required from when the device is on body.

4.4 Body Position and Motion

Body Position and motion are calculated using three orthogonal accelerometer channels and are reported as follows:

- Prone (lying down - face down)
- Supine (lying down -face up)
- Upright
- Side (lying down – right or left side)
- Inverted (upside down)

Motion is reported as:

- None (stationary)
- Low (i.e., walking)
- High (i.e., running)

Motion detection can create an error due to external influences. For example, certain vehicles and terrains may produce patterns similar to ambulatory activity. For this reason, the presence of motion should be used as a supplemental indication and not as a sole means to determine the welfare of a user.

In addition, the raw accelerometer waveforms (gravitational load versus time) may also be transmitted from the EQ02+ EX SEM. These waveforms may be used to derive additional motion and activity measures by third party or bespoke software programmes.

4.5 Alerts and Alarms

The Equivital™ Manager application enables the quick configuration of an EQ02+ EX SEM for a variety of applications. For further details, refer to the Equivital™ Manager User Guide.

Once the EQ02+ EX SEM determines that certain conditions have been exceeded within the measured physiology, it sends Alerts and Alarms.

ECG Alerts

Heart Rate High (Tachycardia) Indication

The measured Heart Rate exceeds the customised tachycardia threshold in the EQ02+ EX SEM.

Heart Rate Low (Bradycardia) Indication

The measured Heart Rate falls below the customised bradycardia threshold in the EQ02+ EX SEM.

Irregular Rhythm/Noise Alert

The measured ECG inter beat interval variation exceeds the customised threshold in the EQ02+ EX SEM. This may be due to an irregular rhythm or high degree of noise on the ECG due to motion or incorrectly fitted belt.

Breathing Rate Alert

Breathing Rate High Indication

The measured Breathing Rate exceeds the customised high Breathing Rate threshold in the EQ02+ EX SEM.

Breathing Rate Low Indication

The measured Breathing Rate falls below the customised low Breathing Rate threshold in the EQ02+ EX SEM.

Short-Term Breathing Rate Alert

The EX SEM has not detected a breath for a defined time window. This window is normally set to be shorter than the normal Breathing Rate window to provide early indication of possible respiratory distress.

The time window may be customised in the EQ02+ EX SEM.

Physiological Welfare Indicator (PWI)

Because the EQ02 EX LifeMonitor may be used remotely to monitor Subjects, an additional Vital Signs alert/indication is provided which is an aggregation of the earlier alerts and alarms measured by the device. This may assist the HCP in more rapid detection of Subjects displaying unexpected physiology or multiple alerts/alarms.

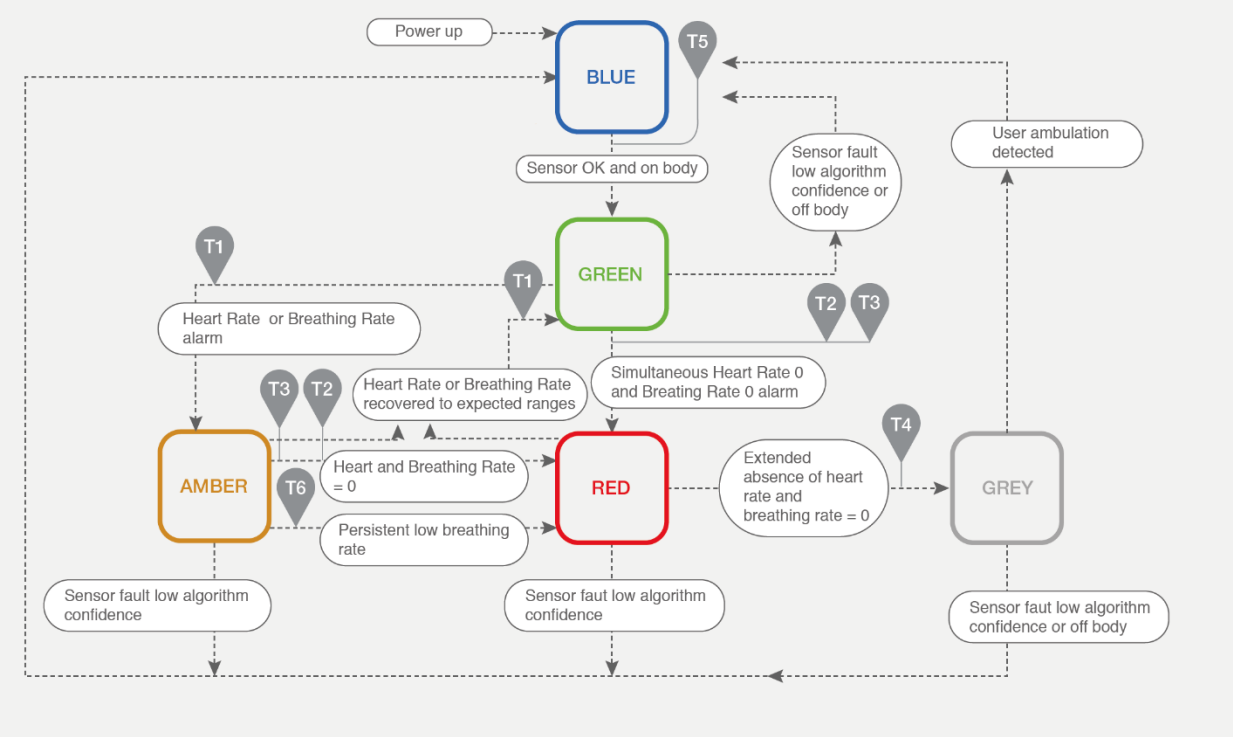

Figure 13 PWI Indication Outputs (see Table 6 for transition times T1-T6 above)

This combined indicator uses a colour-coded scheme related to the vital signs physiology measured:

Red = Alarm – High risk physiology

Amber = Alert – Indication that physiology is outside expected boundaries and requires closer scrutiny

- Green = Normal – Physiology is within expected boundaries
- Grey = Absence of detectable physiological signals for a sustained time period
- Blue = Device in an inoperative or inconclusive state

The colour designations of the PWI indicator should not be assumed to denote clinical priority or urgency. The health care professional is responsible for making this decision on a case-by-case basis.

- The boundaries and settings are defined within the EQ02+ EX SEM (see EQ02+ EX SEM Configuration Data). The setting of the indication output is defined as per the state transition diagram shown in Figure 13.
- As well as using the current physiological values to determine the output value of this indicator the EX SEM also uses an overall Vital Signs confidence value associated with the Heart and Breathing Rate measures. This value is based on the confidence measures for Heart and Breathing Rates discussed earlier. It is intentionally biased towards Breathing Rate Confidence, reflecting its primary triage importance.
- This allows the EX SEM to reduce false indications by avoiding raising the combined Physiological Welfare Indicator if the underlying cardio-respiratory data is noisy due to external influences as the overall confidence measure will be lower in this case. Note that in this case the device state output indicates BLUE and does not assume a normal (non-alerting) state. This is so that monitoring personnel can take appropriate action to investigate and rectify the cause.
- The PWI indicator is reported every 15 seconds and is permanently enabled.

Fall Alarm

The EQ02+ EX SEM uses the built-in tri axis accelerometer to monitor upright to non-upright transitions that may be indicative of a fall event. If the correct combination of rapid changes of accelerometer data and change to a non-upright position are detected the EX SEM will indicate a Fall Suspected.

After the EX SEM has registered a Fall Suspected it can also progress to issuing a Fall Confirmed alarm.

In order for the EQ02+ EX SEM to send a Fall Confirmed alarm there needs to be a period of no movement following a Fall Suspected. The period of 'No Movement' can be set by the User (see EQ02+ SEM Configuration Data).

5 EQ02+ EX SEM Configuration Data

5.1 Default Settings

The following list covers the parameters that are intended for configuration by the system's User. Other parameters exist in the device but are not configurable by the User as standard.

Data is logged and stored locally on the EQ02+ EX SEM, irrespective of other parameters, e.g. Partial and Full disclosure

It is advisable to check the factory default settings using Equivital™ Manager to ensure that the EQ02+ EX SEM defaults have not changed.

PARAMETER	DESCRIPTION	DEFAULT
Bluetooth Connectivity	This enables the connectivity to the radio interface in the EX SEM. If this parameter is ENABLED, power will be applied to the radio and hence the EX SEM can communicate wirelessly. DISABLING this parameter will save battery power and hence increase the EX SEMs ON time, for Subjects who do not need to communicate wirelessly.	ENABLED
Bluetooth PIN	PIN used to allow connection to the EX SEM via Bluetooth. It is recommended that the User modify this PIN from the factory default. The range that can be used is 4-15 digit numeric	1111
Live Data Transmission	This parameter can be set to FULL or PARTIAL DISCLOSURE. If set to the former the Live data output from the EX SEM will include Live Waveforms in addition to Summary data. The use of PARTIAL DISCLOSURE during Live transmission will improve the EX SEM battery life and may also be preferred if data bandwidth limitations are present It should be noted that irrespective of this setting Full Disclosure data is stored internally on the EX SEM	FULL DISCOSURE
Heart Rate Reporting	The HR can be reported every 5-seconds or every 15-seconds	15s

PARAMETER	DESCRIPTION	DEFAULT
Expansion Derived Breathing	Sets the EX SEM to output Breathing Rates calculated from the belt respiration sensor	ENABLED
ECG Derived Breathing	Sets the EX SEM to output Breathing Rates derived from the ECG signal	DISABLED
Body Temperature Sensors	This will allow Core Pill and Dermal Patch data to be received and output by the EX SEM if ENABLED. DISABLING this parameter will save battery power and hence increase the EX SEMs ON time, for Users who do not need this feature.	ENABLED
Usage Mode	This allows the filtering method for the ECG signal for to be set for the patient anticipated use case of AMBULATORY or CLINICAL (sedentary).	AMBULATORY
ECG Processing	Specifies whether the EX SEM should use both leads (STANDARD) or only the ECG1 lead (USE ECG 1 ONLY) for Heart Rate data	STANDARD
Accelerometer	This specifies whether the EX SEM should log High-resolution (256Hz) accelerometer data to the SD card. This is in addition to STANDARD resolution data, which is always logged.	STANDARD
Fall Detection	The EX SEM can be configured such that Fall Detection is ENABLED or DISABLED	ENABLED
Lead Off Alarm	The Lead Off alarm indicates that the ECG electrode signal quality is poor. It can be ENABLED or DISABLED by the User.	ENABLED
Real Time Clock	The Real Time Clock of the EX SEM can be set to UTC or to the Computer's local time. It is recommended that the EX SEM be set to UTC.	UTC
Wake Up Settings	This specifies if the EX SEM is ENABLED to sleep periodically.	DISABLED

PARAMETER	DESCRIPTION	DEFAULT
	If ENABLED after the EX SEM is turned on, it will remain awake for the Duration specified and then will turn off. The EX SEM will then turn on at the specified Interval.	
Sensor Power Button	The EX SEM can be configured such that the ability to turn it off manually by pressing the power button is ENABLED or DISABLED.	ENABLED
USB Connection Removed	The EX SEM can be configured to turn OFF or remain ON when the USB connection is removed	ON

Table 3 EQ02+ EX SEM Default Configuration Settings

5.2 Alerts, Alarm Limits & Time Thresholds

User Configurable

PARAMETER	PARAMETER NAME	DESCRIPTION	RANGE	DEFAULT
Tachycardia limit	HR High Threshold	Tachycardia limit for Heart Rate	1-255 bpm	220 bpm
Bradycardia limit	HR Low Threshold	Bradycardia limit for Heart Rate	1-255 bpm	45 bpm
Upper Respiration Limit	BR High Threshold	Upper respiration limit for Breathing rate	1-60 rpm	60 rpm
Lower Respiration Limit	BR Low Threshold	Lower respiration limit for Breathing rate	1-60 rpm	4 rpm
$Sp0_2$ Alarm Threshold	Oxygen Saturation Low Alarm setting	Lower limit for oxygen saturation percentage	0-100%	95%
No Breath Time Limit	No Breath Alarm	Specifies the time in seconds of No Breath detected after which the EX SEM will send an alarm	0-255 sec	45 sec

PARAMETER	PARAMETER NAME	DESCRIPTION	RANGE	DEFAULT
No Movement Threshold	Post-Fall no movement threshold	Specifies how long, in seconds, the Subject must remain motionless following a Fall Suspected before a Fall Confirmed alarm is sent by the EX SEM	0-160 sec	15 sec

Table 4 EQ02+ EX SEM Alerts, Alarm Limits & Time Thresholds

For the HR and BR high/low threshold levels a value of '0' corresponds to no threshold having been set

Set Configuration

The following parameters are not User configurable.

Confidence Thresholds

PARAMETER	PARAMETER NAME	DESCRIPTION	DEFAULT
Heart Rate Confidence Threshold	HR Confidence Threshold	Minimum confidence in Heart Rate signal needed to make an alarm or alert condition	80%
Breathing Rate Confidence Threshold	BR Confidence Threshold	Minimum confidence in Breathing Rate signal needed to make an alarm or alert condition	80%

Table 5 EQ02+ EX SEM Confidence Thresholds Configurations – not User configurable

PWI Specific

Please refer to Figure 13 for the transitions related to the Time Thresholds in Table 6.

10.5	PARAMETER NAME	DESCRIPTION	DEFAULT
Combined indication operational confidence threshold	Minimum Operational Confidence	Minimum PWI algorithm confidence below which the output is considered unreliable and should be set to unknown or inoperative (BLUE)	45%

10.5	PARAMETER NAME	DESCRIPTION	DEFAULT
Threshold Exception Time	Time Threshold 1 (T1)	Time required for an out of threshold rate to exist before an indication is raised. A setting of 0 minutes corresponds to an effective update time of 15-seconds.	0 minutes
Time to alert – cardiac alarm	Time Threshold 2 (T2)	Period when HR = 0 before an indication is raised.	15 seconds
Time to alert – breathing alarm	Time Threshold 3 (T3)	Period when BR = 0 before an indication is raised	15 seconds
Time Threshold – Sustained absence of cardiorespiratory signals	Time Threshold 4 (T4)	Period to transition from RED to GREY state when no vital sign signals are being measured.	2 mins
Time Threshold – Sensor Initialisation	Time Threshold 5 (T5)	Period to transition from BLUE to GREEN state once the sensor PWI algorithm confidence is above minimum threshold.	1 min
Time Threshold – Low Breathing Rate alarm whilst alert active	Time Threshold 6 (T6)	Period to transition from AMBER to RED state if very low Breathing Rate (< 2 rpm) is observed	2 seconds

Table 6 EQ02+ EX SEM PWI Specific Configurations – not User configurable

6 Appendices

6.1 Technical Specifications

EQO2+ EX LifeMonitor Device Classification

PARAMETER	SPECIFICATION
Hazardous Area Classification	Intertek 4008149 Conforms To UL Std 913 Certified To CSA Std C22.2 No. 60079-0 and No. 60079-11 Class I Div.1, Group C & D, T4 Exia -20°C ≤ Ta ≤ + 50°C ITS13ATEX27919X I M1 Ex ia I Ma II 1G Ex ia IIB T4 Ga
FDA Medical Device Classification	Class II
EU Medical Device Classification	Class IIb (EQ02 EX SEM) Class I (EQ02 EX Sensor Belt)
Electrical Shock Protection	Type BF Applied Part, Internally Powered Equipment *IEC 60601-1*
Mode of Operation	Continuous
Water Ingress Protection	IPx7

Table 7 EQ02+ EX LifeMonitor Device Classification

IPx7 is only applicable when the EQ02 EX SEM and EQ02 EX Sensor Belt are connected together as described in this guide

IPx7 means waterproof when submerged up to 1 metre for 30 minutes

During immersion in water the EQ02 EX LifeMonitor is not guaranteed to provide accurate physiological data

After immersion in water the EQ02 EX LifeMonitor (EX SEM and EX Sensor Belt) will need to dry out in order to provide accurate physiological data

EQ02+ EX Sensor Belt

PARAMETER	SPECIFICATION
Duration of Continuous Use	24-hours
Operating temperature	-10°C to +50°C *BS EN 60068-2-1: Cold* *BS EN 60068-2-78: Damp Heat Steady State*
Storage Temperature	-20°C to +55°C *BS EN 60068-2-1: Cold* *BS EN 60068-2-78: Damp Heat Steady State*
Operating and Storage Humidity	0% to 95%, Relative Humidity, Non-Condensing *BS EN 60068-2-78: Damp Heat Steady State*
Altitude	-300 to 30,000 feet *BS EN 60068-2-13: Low Air Pressure*
Expected Service Life	6 months based on normal wash and wear cycles

Table 8 EX Sensor Belt environmental specification

EQ02 M Dock

Parameter	Specification
Operating Environment	For indoor use only
Operating temperature	0°C to +40°C
Storage Temperature	-20°C to +65°C
Storage Humidity	5% to 95%, Relative Humidity, Non-Condensing
Expected Service Life	10 years based on normal docking and undocking use cycles

Table 9 EQ02+ M Dock environmental specification

EX Sensor Electronics Module (SEM)

General

PARAMETER	SPECIFICATION
Size (overall dimensions)	78mm x 55mm x 11mm
Weight	60g
Operating temperature	-20°C to +50°C *BS EN 60068-2-1: Cold* *BS EN 60068-2-78: Damp Heat Steady State*

PARAMETER	SPECIFICATION
Storage Temperature	-20°C to +55°C *BS EN 60068-2-1: Cold* *BS EN 60068-2-78: Damp Heat Steady State*
Operating and Storage Humidity	0% to 95%, Relative Humidity, Non-Condensing *BS EN 60068-2-78: Damp Heat Steady State*
Altitude	-300 to 30,000 feet *BS EN 60068-2-13: Low Air Pressure*
Power	3.7V 300mA Lithium-Polymer rechargeable cell
Operating Time	Full Disclosure – 35 hours, typical (Bluetooth Disabled and no accessories)
Li Polymer Recharge Time	From Flat ~2hr
Charging Temperature	10°C to +40°C
Expected Service Life	5 years based on battery life of 300 use cycles

The EX SEM should not be charged at temperatures below 10°C, as this will significantly reduce the charge retained by the EX SEM and hence the available operating time. It is recommended to charge the EX SEM above 20°C.

Table 10 EQ02+ EX SEM - environmental and general specification

ECG

PARAMETER	SPECIFICATION	
Number of leads	2	
Sampling frequency	256 Hz	
Resolution	10 bits	
Voltage range	+/- 5mV	
Frequency Range	Clinical/Diagnostic Setting:	0.3 – 50 Hz (3dB points)
	Motion/Ambulation Setting:	7Hz – 50Hz (3dB points)
Heart Rate Range	0 – 300 bpm	
Heart Rate Calculation Frequency	5 or 15 seconds (User selectable in Equivital™ Manager)	
Heart Rate Accuracy	<+/-5bpm/10%	

Table 11 EQ02+ EX SEM - ECG Parameters

Chest Expansion Respiration Effort

PARAMETER	SPECIFICATION
Measurement type	Resistive strain gauge
Sampling frequency	25.6 Hz
Resolution	10 bits
Frequency Range	0.05 – 7 Hz
Breathing Rate Range	0 – 60 rpm
Breathing Rate Accuracy	+/- 2 rpm Static Use +/- 3 rpm Moderate Ambulation Activity (e.g. walking) +/- 6 rpm High Ambulation Activities (e.g. running/heavy carrying)
Breathing Rate Reporting Frequency	15 seconds

Table 12 EQ02+ EX SEM - Respiration Parameters

Skin Temperature

For accurate skin temperature measurements an initial settling time, of approximately 15-minutes, is required from when the device is on body

PARAMETER	SPECIFICATION
Sampling frequency	0.25Hz
Resolution	10 bits
Range	–10°C to +50°C
Sensor Accuracy	32°C to 42°C = ±0.3°C 0°C to 50°C = ±0.5°C -10°C to 50°C = ±1.5°C
Measurement Type	IR Skin Temperature
Temperature Reporting Frequency	15 seconds

Table 13 EQ02+ EX SEM - Skin Temperature Parameters

ANSI/AAMI EC 13 Performance Disclosure

The following section covers disclosure of performance requirements against tests specified in EC13 Cardiac Monitors, heart rate meters and alarms.

These settings apply when the EQ02+ EX SEM is set to its clinical/diagnostic filter setting and has 5 second reporting rate for Heart Rate enabled.

For details of the tests, refer to the ANSI/AMEE Standard:

- 4.1.2.1 (a) – Electrosurgery - See Contraindications
- 4.1.2.1 (b) – Lead Off Sensing – See Technical Specifications
- 4.1.2.1 (c) - Tall T Wave Rejection: The maximum T wave amplitude supported before the Heart Rate exceeds the rated 10% tolerance, relative to a 1mV QRS deflection is 0.8mV
- 4.1.2.1 (d) – Heart Rate Averaging – See Heart Rate Calculation
- 4.1.2.1 (e) - Heart Rate Meter Accuracy and response to irregular waveforms (as specified in the EC13 standard):

  3a) Ventricular Bigeminy: Recorded result = 40bpm

  3b) Slow Alternating Ventricular Bigeminy: Recorded result = 30bpm

  3c) Rapid Alternating Ventricular Bigeminy: Recorded result = 60bpm

  3d) Bidirectional Systoles: Recorded result = 90bpm

- 4.1.2.1 (f) Response time of heart rate meter to change in Heart Rate

  80bpm – 120 bpm: 6s – 8s; mean 7s

  80bpm – 40 bpm: 7s – 11s; mean 9s

- 4.1.2.1 (g) Time to Alarm for Tachycardia:

  Waveform 4a): 3s – 6s; mean 5s

  Waveform 4a) halved: 3s – 9s; mean 5s

  Waveform 4a) doubled: 1s – 6s; mean 4s

  Waveform 4b): 1s – 6s; mean 4s

  Waveform 4b) halved: 3s – 7s; mean 6s

  Waveform 4b) doubled: 2s – 6s; mean 4s

- 4.1.2.1 (h) – Pacemaker rejection – The device is contraindicated for pacemaker equipped patients.
- 4.1.2.1 (i),(j) – Not applicable – The device is a telemetry module intended to provide data for a separate viewer product. The alerts provided by the Hidalgo supplied viewer are documented in its user manual
- 4.1.2.1 (k) Battery power information – See Technical Specifications
- 4.1.2.1 (l) Telemetry: - See Technical Specifications – General and EMC
- 4.1.2.1 (m) Not applicable
- 4.1.2.1 (n) Not applicable – the device does not contain its own integral ECG viewing function
- 4.1.2.1(o) Not applicable – device uses specific electrode
- 4.1.2.1(p) Auxiliary output - Not applicable
- 4.1.2.1(q) See Instructions for Use
- 4.1.2.1(r) Battery disposal – See Technical Specifications

- 4.1.2.2 Application Notes – See Instructions for Use
- 4.1.3 Service – See Instructions for use
- 4.1.4 Pacemaker additional information – contraindicated

Electro Magnetic Compatibility (EMC)

This device has been designed to meet the relevant radio and electromagnetic interference standards for the countries where it is to be used.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

EQ02+ EX LifeMonitor Use Environment

The Equivital™EQ02+ EX LifeMonitor is intended for use in the electromagnetic environment specified below. The customer or the User of the EQ02+ EX LifeMonitor should assure that it is used in such an environment.

The EQ02+ EX LifeMonitor is not suitable for interconnection with other equipment.

The EQ02+ EX LifeMonitor is suitable for use in all establishments including those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

The EQ02+ EX LifeMonitor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled.

Electro Magnetic Disturbance Impact on Essential Performance

Please see Tables 13 through 16 for the information on the electromagnetic environment under which the LifeMonitor is intended for use.

The customer or the User of the EQ02+ EX LifeMonitor should assure that it is used in such an environment to guarantee the intended performance of the LifeMonitor as defined in this document.

Please also see the text following Table 17 for suggestions of remedial action.

EQ02+ EX LifeMonitor and Adjacent Equipment

Use of the EQ02+ EX LifeMonitor adjacent to other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

EQ02+ EX LifeMonitor Accessories

Approved accessories for the EQ02+ EX LifeMonitor are as listed in Section 2.

Only Equivital™ approved accessories are to be used with the Equivital™ EQ02+ EX LifeMonitor. The safe use of the device is only guaranteed with these accessories. Use of other accessories could result in increased electromagnetic emissions or decreased electromagnetic immunity.

EQ02+ EX LifeMonitor and RF Communication Equipment Separation

For safe separation distances, please see Table 17 and related information.

Guidance and Manufacturers Declaration – Electromagnetic Emissions

EN60601-1-2			
Conducted Emissions	EN55011	Table 2b = CISPR22(B)	PASS
Radiated Emissions	EN55011	Table 3 = CISPR22(B)	PASS
Harmonic Currents	EN61000-3-2	EN61000-3-2	Not applicable
Flicker	EN61000-3-3	EN61000-3-3	Not applicable

Table 14 EN60601-1-2 – Electromagnetic Emissions

EN301 489-1 V1.8.1 Class B			
TEST	METHOD	LIMIT	PASS/FAIL
Conducted Emissions	EN55022	Table 6 & 8 = CISPR22(B)	PASS
Radiated Emissions	EN55022	Table 4 = CISPR22(B)	PASS
Harmonic Currents	EN61000-3-2	EN61000-3-2	Not applicable
Flicker	EN61000-3-3	EN61000-3-3	Not applicable

Table 15 EN301 489-1 V1.8.1 Class B – Electromagnetic Emissions

Guidance and Manufacturers Declaration – Electromagnetic Immunity

EN60601-1-2

TEST	METHOD	SEVERITY	CRITERION ACHIEVED
Electrostatic Discharge (ESD)	IEC61000-4-2	Air - 2, 4, 8kV	PASS
		Contact – 2, 4, 6kV	PASS
Radiated Field Immunity	IEC61000-4-3	3V/m 80-2500MHz 1kHz 80% am	PASS
		3V/m 80-2500MHz 2Hz 80% am	PASS
Electrical Fast Transients	IEC61000-4-4	1kV	Not Applicable
		2kV	
Surge	IEC61000-4-5	1: 0kV Line- Line 2: 0kV Line- Earth	Not Applicable
Conducted Field Immunity	IEC61000-4-6	3Vrms 0.15-80MHz 1kHz 80% am	PASS
		3Vrms 0.15-80MHz 2Hz 80% am	Not Applicable
Power Frequency Magnetic Field	IEC61000-4-8	50Hz/60Hz, 3A/m	PASS
Voltage Dips and Interruptions	IEC61000-4-11	> 95% reduction, 10msec	Not applicable
		60% reduction, 100msec	
		30% reduction, 500msec	
		> 95% reduction, 5s	

Table 16 EN60601-1-2 – Electromagnetic Immunity

EN301 489-1 V1.8.1 Class B			
TEST	METHOD	SEVERITY	CRITERION ACHIEVED
Electrostatic Discharge (ESD)	EN61000-4-2	Air - 8kV	TRANSIENT
		Contact – 4kV	TRANSIENT
Radiated Field Immunity	EN61000-4-3	3V/m 80-2700MHz 80% 1kHz am mod	CONTINUOUS
Electrical Fast Transients	EN61000-4-4	0.5kV	Not Applicable
		1kV	
Surge	EN61000-4-5	1: 0kV Line- Line	Not Applicable
		2: 0kV Line- Earth	

EN301 489-1 V1.8.1 Class B			
Conducted Field Immunity	EN61000-4-6	3Vrms 0.15-80MHz 80% 1kHz am mod	CONTINUOUS
Voltage Dips and Interruptions	EN61000-4-11	100% reduction, 10msec	Not applicable
		100% reduction, 20msec	
		30% reduction, 500msec	
		100% reduction, 5s	
Vehicle Transients	ISO 7637-2:2004	Pulse 3a, 3b; Test Level III	Not applicable
Vehicle Surge	ISO 7637-2:2004	Pulse 1, 2a, 2b; Test Level III	Not applicable
Vehicle Dips	ISO 7637-2:2004	Pulse 4; Test Level III	Not applicable

Table 17 EN301 489-1 V1.8.1 Class B – Electromagnetic Immunity

The Equivital™EQ02+ EX LifeMonitor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled.

The customer or User of the EQ02+ EX LifeMonitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EQ02+ EX SEM as recommended in Table 18, based on the maximum output power of the communications equipment.

Recommended separation distances between portable / mobile RF communications equipment & the EQ02 EX SEM			
Rated Max Output Power of Transmitter Watts (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

NOTES

- At 80 MHz and 800MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 18 Recommended Separation distances between RF comms and the EQ02+ EX SEM

For transmitters rated at a maximum output power not listed in Table 18, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, based on its output power, P, in Watts (W) as stated by the transmitter manufacturer. The equations are:

- For Frequency between 150kHz and 80Mhz: d = [3.5/3] x P
- For Frequency between 80Mhz and 800MHz: d = [3.5/3] x P
- For Frequency between 800Mhz and 2.5Ghz: d = [7/3] x P

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level within each frequency range.

The above calculations are for guidance only.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM, FM broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength exceeds the applicable RF compliance level above, the EQ02+ EX SEM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as re-orienting or relocating the EQ02+ EX SEM.

If you are entering a facility where interference may be a particular concern (e.g. a hospital or hazardous plant environment) contact the person in charge of the facility to check if any special precautions need to be taken.

If you experience unwanted interference increase the physical separation between the devices.

If you have specific concerns about the devices compatibility or experience problems that cannot be resolved by increasing separation of the devices, please contact Hidalgo.

FCC Compliance and Advisory Notice (US Markets)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and utilizes radio frequency energy and, if not installed and used in accordance with the instructions for use, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception that can be determined by turning the equipment off and on, the User is encouraged to try to correct the interference by one or more of the following measures:

- Re-orientate or relocate the receiving radio or television antenna.

- Increase the separation between the equipment and the radio or television receiver.
- Connect the equipment into an outlet on a circuit different from that to which the radio or television receiver is connected.
- Consult the dealer or an experienced radio/television technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) these devices must accept any interference received, including interference that may cause undesired operation.

Type 0 Radio Interface:	FCC ID: T85EQ001
Type 1 Radio Interface:	FCC ID: QOQWT11

6.2 Connecting to and Using the EQ02+ EX SEM

Bluetooth™ Connection Information

The EQ02+ EX SEM complies with the Bluetooth™ protocol specification V2.1. It can be used with a Bluetooth™ certified transceiver that supports the serial port profile. This profile allows serial data to be passed over the Bluetooth™ radio and to be presented at the receiver end as a serial data stream communications port.

The EQ02+ EX SEM appears as a “discoverable slave” device that means it can be located and connected to by the receiving unit. See Equivital™ Manager User Guide for instructions on how to initiate the connection.

The User must ensure that Bluetooth™ accessories meet all required approvals for use in a hazardous area

EX SEM Data Security

The Bluetooth™ protocol implements both encryption and authentication using a passkey (PIN) to allow access.

The PIN for the EQ02+ EX SEM should be programmed into the unit by the Equivital Manager Application (See Sensor Configuration Data).

Failure to set a unique Bluetooth™ PIN may compromise the security of the device and may make it easier for other persons to connect to the EQ02+ EX SEM.

Application Protocol Overview

The following information provides a summary list of data disclosed by the EQ02+ EX SEM in Partial (Summary) and Full Disclosure modes.

Summary Disclosure

The following data is transferred every 15 seconds:

- ECG Heart Rate
- Heart Rate Confidence
- Respiration Band Rate (if configured)
- Respiration Rate Confidence
- EDR Rate (if configured)
- EDR Quality (if configured)
- IR Skin Temperature
- Physiological Welfare Index state
- Fall state (if a Fall is Suspected or Confirmed this is sent immediately)
- Respiration Indications
    - Low Breathing Rate
    - High Breathing Rate

The following are sent every 5 seconds:

- ECG Indications:
    - Low Heart Rate
    - High Heart Rate
- Body Position (update also sent immediately if state changes)
- Motion Classification (update also sent immediately if state changes)
- Sensor Fault Codes

Data from the following sensors is sent whenever a value is received:

- Core Pill Temperature
- Dermal Temperature Patch
- Galvanic Skin Response
- Oxygen Saturation (SpO2)

Full Disclosure

When full disclosure is selected, then in addition to the Summary disclosure, the following data can be transmitted, depending upon the configuration:

- Raw Waveform Data

- ECG1 and ECG2
- Respiration Belt Trace
- Accelerometer Traces (all axes)
- Photo Plethysmography, PPG (if available)

Software Development Kit

Hidalgo provides .NET, JAVA and Android SDKs that allow a systems integrator or developer to integrate Equivital EQ02+ EX SEM data into their applications.

6.3 Equivital™ Bluetooth Dongle Specification

Equivital™ provides a dedicated Bluetooth dongle that allows up to 6 EX SEMs in partial disclosure, and 3 in full disclosure, to communicate with a laptop or PC running the Equivital™ Manager.

PARAMETER	SPECIFICATION
Dimensions (excluding USB connector)	Length = 58-mm Width = 22-mm Height = 13-mm
Operating Environment	For indoor use only
Operating Temperature	0°C to +40°C
Storage Temperature	-40°C to +85°C
Operating Humidity	20% to 95%, Relative Humidity, Non-Condensing
Storage Humidity	0% to 95%, Relative Humidity, Non-Condensing
Regulatory Information	 The unit complies with all relevant safety standards  FCC Part 15 approval, FCC ID: QOQWT41  This symbol indicates that the unit cannot be treated as normal domestic trash at disposal, but must be handed in at a collection point for recycling electrical and electronic appliances.
Bluetooth	Class 1

Table 19: Equivital™ Bluetooth Dongle Specification

The Equivital™ Bluetooth Dongle is NOT approved for use in a hazardous area

The Equivital™ Bluetooth Dongle is not approved for use closer than within 25cm of the body. If you application requires closer contact to the body, additional approvals will be required.

If you have any suggestions or feedback for us concerning this guide please contact us on
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